510(k) Summary

FEB 8 2007

1. SPONSOR

Med-Conduit Inc.
18 Derby Lane
Tyngsboro, MA 01879

Contact: Gerald G. Bousquet, M.D.

Date Prepared:

2. DEVICE NAME

Proprietary Name:	HemoCath II
Common/Usual Name:	Central Venous Catheter
Classification Name:	Long-Term Intravascular Catheter
Classification:	78 MSD

3. PREDICATE DEVICES

HEMOCATH-SKIN PORT **510 (K) K043292**

4. DEVICE DESCRIPTION

The HemoCath II is radiopaque silicone, comprised of 2 single lumens used to remove and return blood through two segregated circular lumen passages. The distal venous lumen extends beyond the arterial lumen to reduce recirculation. The fixed Dacron cuff allows for tissue ingrowth for long-term placement.

5. INTENDED USE

The HemoCath II is indicated for use in attaining long term vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

6. SUBSTANTIAL EQUIVALENCE

The HemoCath II is substantially equivalent to a combination of its predicate devices in terms of intended use, design, material type, performance, and method of sterilization.

7. PERFORMANCE TESTING

Information submitted in this premarket notification includes in vitro performance data for the HemoCath II including flow rate and tensile strength that is substantially equivalent to the legally marketed devices.

Clinical data was not deemed necessary since in vitro testing was sufficient to demonstrate safety and efficacy by way of comparison to legally marketed predicate device intended for hemodialysis and apheresis treatments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gerald G. Bousquet, M.D.
President
Med-Conduit, Inc.
18 Derby Lane
TYNGSBORO MA 01879

FEB 8 2007

Re: K062901
Trade/Device Name: HemoCath Hemodialysis/Apheresis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD
Dated: January 16, 2007
Received: January 23, 2007

Dear Dr. Bousquet:

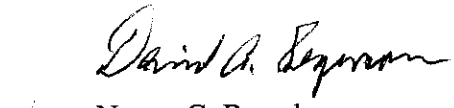
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062901

Device Name: HemoCath Hemodialysis/Apheresis Catheter

Indications for Use: The HemoCath Hemodialysis/Apheresis Catheter is indicated for use in attaining long term vascular access for hemodialysis or apheresis therapy via the jugular or subclavian vein. The catheter is intended for implantation dwell time of greater than 30 days.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062901